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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/10/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,472

Applicant(s)

EINAT ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9, 13 and 14 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 13 and 14 in Paper No. 13 is acknowledged. The traversal is based on Applicants' concession that if the polypeptide of claim 13 was available to the prior art, it would be *prima facie* obvious within the meaning of 35 U.S.C. 103 for one of ordinary skill in the art to make an antibody which is specific to such protein. Based on this admission by the Applicants, the arguments are found to be persuasive and Group III, claim 9 will be rejoined for prosecution.

Applicants are advised that the rejoinder is solely based on Applicants' statement regarding claim 9, wherein the claim is stated to be broad and encompasses antibodies which would not be patentable and would be *prima facie* obvious in the sense of 35 U.S.C. 103 (page 6, response) if the protein was anticipated or obvious in view of the prior art. Under this context, the restriction between the antibody and the protein is withdrawn.

Applicants are advised that if, during prosecution, Applicants amend the antibody claim to recite an "unexpected properties which would not be obvious from prior art knowledge of the protein to which it is specific," (page 5, response), such amendment would elicit a subsequent restriction since such antibody would not be obvious over the protein to which it is specific.

Claims 9, 13, and 14 are pending and are under prosecution.

Claim Objections

Claim 9 is objected to because of the following informalities: Claim 9 depends on a subsequent claim 13. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 13, 14, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Semenza (WO 96/39426, December 12, 1996, IDS ref# BC, paper No. 15).

Claims 13 and 9 are drawn to a polypeptide comprising a protein encoded by a polynucleotide comprising SEQ ID NO: 3, its variant, or **a fragment thereof** which retains the biological activity thereof.

Claim 14 is drawn to a polypeptide comprising a protein of SEQ ID NO: 4, its variant, or **a fragment thereof** which retains the biological activity thereof.

Semenza discloses a purified HIF-1 (hypoxia-inducible factor 1) protein which is expressed hypoxia induced condition in cells (Abstract and page 2). Since claims 13 and 14 contain an embodiment drawn to a polypeptide comprising a fragment of a protein of SEQ ID NO: 4 or a fragment of protein encoded by SEQ ID NO: 3, wherein the term “fragment,” would arguably be a single amino acid, the functional protein disclosed by Semenza would comprise such fragment.

Semenza also discloses an antibody against the purified HIF-1 protein (page 38, lines 30-34).

Therefore, Semenza anticipates the invention as claimed.

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Conclusion

No claims are allowed.

The utility rejection was not made in view of the disclosure that the nucleic acid of SEQ ID NO: 3 and its protein of SEQ ID NO: 4 are differentially expressed in hypoxia-induced cells, rendering the nucleic acid and protein useful as diagnostic agents (pp. 9 and 12 lines 10-15).

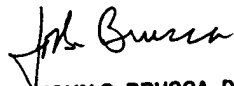
The written description rejection was not made in view of the Sequence Listing disclosing what appears to be a nucleic acid comprising a full open reading frame of SEQ ID NO: 3.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

2/6/03



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER